

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

INFORLIFE SA and  
WG CRITICAL CARE, LLC,

*Plaintiffs,*

V.

SUN PHARMACEUTICAL INDUSTRIES  
LTD., SUN PHARMACEUTICAL  
INDUSTRIES, INC., and HIKMA  
PHARMACEUTICALS USA INC.,

*Defendants.*

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Civil Action No. 21-1740-WCB

## MEMORANDUM OPINION AND ORDER

In this Hatch-Waxman Act patent case, plaintiffs InfoRLife SA and WG Critical Care, LLC, (collectively, “InfoRLife”) allege that the defendants infringe the claims of InfoRLife’s U.S. Patent No. 10,966,990 (“the ’990 patent”). Defendant Hikma Pharmaceuticals has moved under Federal Rule of Civil Procedure 12(c) for judgment on the pleadings, claiming that it does not infringe the asserted claims, either literally or under the doctrine of equivalents. Dkt. No. 84. For the reasons set forth below, the motion is DENIED.<sup>1</sup>

<sup>1</sup> In addition to filing a response to Hikma's Rule 12(c) motion, InfoRLife moved under Federal Rule of Civil Procedure 12(f) to strike Hikma's motion for judgment on the pleadings, Dkt. No. 93, and on the same day InfoRLife filed a three-page letter objecting to Hikma's motion, Dkt. No. 94. The motion to strike is DENIED. First, Rule 12(f) by its terms applies only to striking pleadings and not to motions. *Vidra v. Hertz Corp.*, No. 18-cv-2939, 2018 WL 4853311, at \*2 n.4 (E.D. Pa. Oct. 4, 2018); *Wonderland Nurserygoods Co. v. Thorley Indus., LLC*, No. 12-cv-196, 2013 WL 2471801, at \*1 (W.D. Pa. June 7, 2013); *see also* 5C Charles Alan Wright et al., Fed. Prac. & Proc. Civ. § 1380 & n.8.50 (3d ed., Apr. 2022 update). Second, even if the motion is treated as invoking the court's general authority to strike inappropriate matter, InfoRLife's motion to strike is unnecessary and duplicative, as it covers ground that should properly have been confined to Hikma's opposition to the Rule 12(c) motion. The same can be said for InfoRLife's July 11, 2022, letter, the penultimate paragraph of which requested an adjustment of the date for a

## **I. Background**

The '990 patent is directed to a formulation of midazolam, a short-acting benzodiazepine central nervous system depressant, that is packaged in “flexible plastic container” so that it is “ready-to-use” for intravenous administration. '990 patent, col. 1, ll. 10–12, col. 1, ll. 63–67.<sup>2</sup> Claim 1 is the only independent claim of the '990 patent and is representative of the claimed invention. It recites:

1. A ready-to-use terminally sterilized, preservative-free aqueous midazolam solution in an intravenous laminated flexible plastic bag, comprising 0.25 to 1.5 mg/ml of midazolam, sufficient tonicity adjusting agent to provide an osmolality of from 260 and 320 mosm/kg and sufficient acid and optionally a base to provide a pH of from about 2.5 to 3.5 with the remainder water for injection;

wherein:

the tonicity adjusting agent comprises at least one selected from the group consisting of sodium chloride, potassium chloride and calcium chloride;

the acid comprises hydrochloric acid;

the base, if present, comprises sodium hydroxide; and

the midazolam content after accelerated storage at 40° C. for six months is greater than 97%

the intravenous laminated flexible plastic bag comprises from 3 to 7 layers and has an innermost layer comprises [sic] an ethylene-vinyl acetate copolymer [sic].

'990 patent, claim 1.

Hikma argues that it does not literally infringe the asserted claims because the product described in its abbreviated new drug application (“ANDA”) does not include a flexible plastic

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response to the Rule 12(c) motion, but the rest of which was addressed to objections to Hikma's Rule 12(c) motion. For future purposes, the parties are advised not to file multiple submissions in response to a single motion filed by an opposing party.

<sup>2</sup> The court may consider the '990 patent, its file history, Hikma's ANDA, and InforLife's NDA because those documents are referenced in the complaint and therefore are part of the pleadings. *See In re Bendamustine Consol. Cases*, No. 13-cv-2046, 2015 WL 1951399, at \*1 (D. Del. Apr. 29, 2015).

bag with an innermost layer that comprises an ethylene-vinyl acetate (“EVA”) copolymer. Hikma’s ANDA indicates that the bag of its accused product has an innermost layer that comprises [REDACTED]. Dkt. No. 69-1, Exh. 4. Hikma also argues that it does not infringe under the doctrine of equivalents due to prosecution history estoppel and the disclosure-dedication rule. InfoRLife responds that there are factual disputes that preclude a grant of judgment on the pleadings with respect to both literal infringement and the doctrine of equivalents.

## **II. Legal Standard**

Under Federal Rule of Civil Procedure 12(c), “[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings.” A Rule 12(c) motion “will not be granted unless the movant clearly establishes that no material issue of fact remains to be resolved and that [the movant] is entitled to judgment as a matter of law.” *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290 (3d Cir. 1988) (internal quotation marks and citation omitted). The standard that applies to a Rule 12(b)(6) motion to dismiss for failure to state a claim also applies to motions brought under Rule 12(c); that is, in the common situation in which the defendant moves to dismiss the complaint, the court “must accept the truth of all factual allegations in the complaint and must draw all reasonable inferences in favor of the non-movant.” *Revell v. Port Auth. of New York, New Jersey*, 598 F.3d 128, 134 (3d Cir. 2010). More generally, “[t]he purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and documents incorporated by reference.” *Venetec Int’l, Inc. v. Nexus Med., LLC*, 541 F. Supp. 2d 612, 617 (D. Del. 2008).

### III. Discussion

Hikma moves for judgment that it does not infringe literally or under the doctrine of equivalents. I address the issues of literal infringement and infringement under the doctrine of equivalents separately below.

#### A. Literal Infringement

Hikma argues that it does not literally infringe the asserted claims because the flexible plastic bag in its accused product has [REDACTED] rather than an EVA copolymer, as required by the claims. Hikma admits, however, that [REDACTED]. Dkt. No. 85 at 2. InfoRLife argues that the term “flexible plastic bag” in claim 1 should be construed to include the port tube, whereas Hikma argues that the term covers only the bag and not the port tube. InfoRLife also argues that regardless of how the term “flexible plastic bag” is construed, there are factual disputes regarding whether the innermost layer of the plastic bag in Hikma’s accused product comprises EVA.

I need not address the claim construction issue because the pleadings do not make it clear under either party’s construction whether Hikma’s plastic bags lack an innermost layer comprising EVA.<sup>3</sup> InfoRLife alleges in its complaint that Hikma’s “flexible plastic bag comprises from 3 to 7 layers and has an innermost layer comprising an [EVA] copolymer.” Dkt. No. 61 ¶ 33. Hikma’s ANDA [REDACTED]. Dkt. No. 69-1, Exh. 4. Hikma explains that “Hikma’s ANDA does not state that there is EVA in the inner layer” of the plastic bag, Dkt. No. 122 at 5, but the absence of

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<sup>3</sup> In any event, “it is inappropriate to conduct a claim construction analysis at the pleading stage.” *Impossible Foods Inc. v. Motif Foodworks, Inc.*, No. 22-311, Dkt. No. 31 at 4 (D. Del. Nov. 14, 2022); *see also Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1349 (Fed. Cir. 2018) (noting that a dispute regarding claim construction is “not suitable for resolution on a motion to dismiss”). For that reason, the existence of a claim construction dispute would serve as an independent basis to deny Hikma’s motion with respect to literal infringement.

such a statement in the ANDA does not conclusively establish [REDACTED].<sup>4</sup> Accordingly, viewing the facts in the light most favorable to InfoRLife, Hikma has not established, at this stage of the case, that it is entitled to judgment as a matter of law of no literal infringement.

## **B. Doctrine of Equivalents**

Hikma also argues that it does not infringe the claims of the '990 patent under the doctrine of equivalents. For purposes of the doctrine of equivalents discussion, I will assume that the inner layer of Hikma's plastic bag does not comprise EVA (although, as noted above, there is a factual dispute with respect to that issue).

### *1. Prosecution History Estoppel*

Hikma argues that prosecution history estoppel precludes the application of the doctrine of equivalents to plastic bags that have an innermost layer not comprising EVA. During prosecution of the '990 patent, the inventor amended claim 1 to add a limitation requiring that "the laminated flexible plastic bag ha[ve] an innermost layer compris[ing] an ethylene-vinyl acetate copolymer." Dkt. No. 86-1, Exh. 17, at 2. In Hikma's view, that amendment to claim 1 precludes any equivalents that do not have an innermost layer comprising EVA.

Prosecution history estoppel "prevents a patentee from recapturing through the doctrine of equivalents the subject matter that the applicant surrendered during prosecution." *Integrated Tech.*

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<sup>4</sup> Hikma points to additional evidence that it argues supports its position, such as an infrared spectrum of the [REDACTED]. See Dkt. No. 85 at 4. Those documents, which are attached to Hikma's answer, may not be considered for purposes of the present motion. *Horsley v. Feldt*, 304 F.3d 1125, 1134 (11th Cir. 2002) (holding that the "incorporation by reference" doctrine that applies to Rule 12(b)(6) motions also applies to Rule 12(c) motions because "[o]therwise, the conversion clause of Rule 12(c) would be too easily circumvented and disputed documents attached to an answer would have to be taken as true at the pleadings stage"); see also *Lively v. WAFRA Inv. Advisory Grp., Inc.*, 6 F.4th 293, 302 n.2 (2d Cir. 2021) ("[W]hen a defendant moves for judgment on the pleadings, the court may review only those documents that would be appropriate to consider on a motion to dismiss.") (citing *Horsley*, 304 F.3d at 1134–35).

*Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1356 (Fed. Cir. 2013). The doctrine presumptively applies when the applicant makes a “narrowing claim amendment relating to patentability.” *Id.* A patentee may rebut the presumptive application of prosecution history estoppel by establishing that one of three exceptions applies: (1) the equivalent was unforeseeable at the time of the application; (2) the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; or (3) there is some other reason suggesting that the patentee could not reasonably be expected to have described the equivalent. *Id.*; *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740–41 (2002).

Assuming that the amendment to claim 1 was narrowing, InfoRLife argues that it has rebutted the presumption of prosecution history estoppel because the rationale underlying the amendment is only tangentially related to the proposed equivalent and because the proposed equivalent was unforeseeable. On the issue of tangential relation, the parties dispute whether the description of the “flexible plastic bag” was intended to distinguish claim 1 from other prior art containers (e.g., plastic vials or ampoules) or from other functionally equivalent plastic bags. The tangential relation issue is frequently the subject of expert testimony, and I find that in this case further development of the record is necessary to resolve that issue. *See Silvergate Pharms, Inc. v. BionPharma Inc.*, No. 18-1962, Dkt. No. 135 at 71 (D. Del. May 5, 2020) (denying leave to file a Rule 12(c) motion in part because the court would “benefit [from] and, in fact, need the assistance of an expert to understand the full context of the totality of the prosecution history, what the impact of the amendment was, [and] what a person of skill in the art would understand the arguments to mean”).

On the issue of foreseeability, Hikma cites to four documents: two United States patent applications, a German patent application, and a publicly available FDA document. *See* Dkt. No.

85 at 14–15. It is true that the court may take judicial notice of patent applications and FDA documents because they are public records. *See Betak v. Miftakhov*, No. 19-CV-02516, 2019 WL 5684523, at \*5–6 (N.D. Cal. Nov. 1, 2019) (taking judicial notice of two U.S. patent applications); *GeoVector Corp. v. Samsung Elecs. Co.*, 234 F. Supp. 3d 1009, 1016 n.2 (N.D. Cal. 2017) (taking judicial notice of a Korean patent application); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 879 (N.D. Cal. 2013) (collecting cases in which courts have taken judicial notice of FDA documents); *see also* Fed. R. Evid. 201(b)(2). However, courts typically do not take notice of the contents of those documents “as it concerns the prior art relevant to the” asserted patents. *Betak*, 2019 WL 5684523, at \*5. Accordingly, I take judicial notice of the “authenticity and existence” of the four documents relied upon by Hikma, but I do not rely on their contents as evidence of the state of the art or the extent to which InfoRLife’s proposed equivalent was foreseeable. *See Eidson*, 981 F. Supp. 2d at 879; *see also Betak*, 2019 WL 5684523, at \*5.

In any event, “objective unforeseeability depends on underlying factual issues relating to, for example, the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369, 1371 (Fed. Cir. 2003) (en banc) (remanding the issue of foreseeability to the district court to resolve such factual issues). That is another issue on which further development of the record is needed, such as through expert testimony. It would therefore be improper to enter judgment of non-infringement under the doctrine of equivalents “at the pleadings stage in this ANDA case where the file history is highly technical and hotly disputed by the parties.” *See Amgen Inc. v. Alkem Lab ’ys Ltd.*, No. 17-cv-815, 2017 WL 6493150, at \*2 (D. Del. Dec. 19, 2017).

## 2. Disclosure-Dedication Rule

Hikma also argues that the disclosure-dedication rule precludes the application of the doctrine of equivalents to a [REDACTED]. The disclosure-dedication rule provides that “when a patent drafter discloses but declines to claim subject matter,” that subject matter is dedicated to the public. *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc). For the rule to apply, there must be a “clear, precise disclosure” of “explicit alternatives to the inventions claimed.” *PSC Computer Prods., Inc. v. Foxconn Int’l, Inc.*, 355 F.3d 1353, 1358 (Fed. Cir. 2004). That disclosure “must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed,” i.e., it must amount to more than a “generic reference.” *Id.* at 1360. Moreover, the unclaimed subject matter “must have been identified by the patentee as an alternative to a claim limitation.” *SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1364 (Fed. Cir. 2012) (citation omitted).

The specification of the ’990 patent provides that a number of polymeric materials may be used to form the plastic bag, including “polysulfone, polycarbonate, polypropylene, polyethylene . . . , ethylene/propylene copolymers, [and] *polyolefins*.” ’990 patent, col. 4, ll. 43–46 (emphasis added). Although the specification discloses the use of “polyolefins” generally, it does not disclose [REDACTED]. *See* ’990 patent, col. 4, ll. 43–49. Moreover, claim 1 requires that the innermost layer of the plastic bag “comprise[]” EVA; in other words, the claim does not appear to preclude the use of other materials in the innermost layer of the bag as long as EVA is present. The materials disclosed in column 4 of the ’990 patent thus do not appear to necessarily constitute “alternative[s]” to the limitation requiring that the innermost layer comprise EVA. *See SanDisk*, 695 F.3d at 1364.



It is possible that, on a more developed record, the evidence will show that a skilled artisan would have understood the disclosure of the '990 patent to disclose [REDACTED] as an alternative to the EVA copolymer recited in claim 1. At this point, however, Hikma has failed to show that the dedication-disclosure rule applies to the claims of the '990 patent. Hikma is therefore not entitled to judgment as a matter of law of non-infringement under the doctrine of equivalents.

#### **IV. Conclusion**

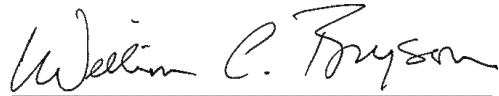
For the reasons set forth above, Hikma's motion for judgment on the pleadings is DENIED.

During an earlier hearing in this case, Chief Judge Connolly ruled that, consistent with the scheduling order and the common practice in ANDA cases, he would not permit the parties to file summary judgment motions in this case. Dkt. No. 48 at 10–11. If, following discovery and claim construction, any party believes that filing a summary judgment motion might simplify proceedings at a trial or obviate the need for trial altogether, I will entertain a request or requests for leave to seek summary judgment at that time. Any such request to file a summary judgment motion will be due within 14 days of the close of expert discovery and must be accompanied by the party's proposed motion for summary judgment.

In an abundance of caution, this order has been filed under seal because the parties' briefs and exhibits regarding the present motions were filed under seal. *See, e.g.*, Dkt. Nos. 85–86, 111–13, 116. Within three business days of the issuance of this order, the parties are directed to advise the court by letter whether they wish any portions of the order to remain under seal. Any request that portions of the order should remain under seal must be supported by a particularized showing of need to limit public access to those portions of the order.

IT IS SO ORDERED.

SIGNED this 21st day of November, 2022.

A handwritten signature in black ink, reading "William C. Bryson". The signature is written in a cursive style with a horizontal line underneath the name.

WILLIAM C. BRYSON  
UNITED STATES CIRCUIT JUDGE